Title: ENDOCARDIAL LEAD FOR A LEFT HEART CHAMBER

REMARKS

This responds to the Office Action dated March 2, 2006, and the references cited therewith.

No claims are amended or cancelled. Claims 1-5, 7-20, and 24 are pending in this application.

§103 Rejection of the Claims

Claims 1, 5, 7, 9, 10, 17, 18 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon (U.S. Patent No. 5,861,023) in view of McAuslan (U.S. Patent No. 4,836,884) and Helland et al. (U.S. Patent No. 5,318,572).

Claims 1, 5, 7, 9, 10, and 24

Applicant traverses the rejection of claims 1, 5, 7, 9, 10, and 24. Applicant believes claim 1 is not obvious in view of the cited references since, even if combined, the references do not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination a lead "wherein the outer surface of the lead body is adapted such that a pseudo-intimal layer is formed on the outer surface when exposed to a bloodstream," as recited in claim 1. In contrast, Vachon discusses an implantable lead which includes material "for minimizing adhesion and tissue ingrowth." (Abstract). Helland does not describe anything about the lead body outer surface. The McAuslan reference discusses a modified implantable hydrogel. (Abstract). But nowhere in the McAuslan reference is the modified hydrogel specifically discussed as being applied to a lead body.

Moreover, Applicant traverses the combination of the cited references since there is no suggestion in the art to combine the references as suggested by the Office Action. Again, Vachon discusses a lead constructed to minimize adhesion and tissue ingrowth (Abstract). On the other hand, Helland discusses an electrode designed for promoting tissue ingrowth. (Col. 3, line 15), and McAuslan discusses a modified hydrogel to stimulate the attachment and growth of cells thereto. (Abstract). Accordingly, one of skill in the art would not be motivated to combine either of these two references with the Vachon reference. Combining Helland or McAuslan with Vachon by altering Vachon to include the porous coating of Helland or the hydrogel of

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McAuslan would destroy the stated purpose of Helland, which is to minimize "adhesion and tissue ingrowth." (Abstract). Applicant notes that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPO 1125 (Fed. Cir. 1984); MPEP § 2143.01.

Moreover, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01. Here, the Examiner has provided hindsight analysis which completely ignores the stated purpose and function of the primary reference, Vachon, so as to piece together an obviousness rejection. There is no indication in the references themselves of any problems with Vachon that the other references allegedly solve. Accordingly, the Examiner's hindsight analysis is the only supposed motivation of combining the references.

Claims 5, 7, 9, 10, and 24 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

Claims 17 and 18

Applicant traverses the rejection of claims 17 and 18. Applicant believes claim 17 is not obvious in view of the cited references since, even if combined the references do not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination a lead including means for passively preventing clots on the lead body that includes forming the lead body such that a pseudo-intimal layer is formed on an outer surface of the lead body when exposed to a bloodstream, as recited in claim 17. A discussed, Vachon discusses an implantable lead which includes material "for minimizing adhesion and tissue ingrowth." (Abstract).

McAuslan discusses a modified hydrogel, and Helland does not describe anything about the lead body outer surface.

Again, Applicant traverses the combination of the cited references since there is no suggestion in the art to combine the references as suggested by the Office Action. As noted, Vachon discusses a lead constructed to minimize adhesion and tissue ingrowth, while Helland discusses promoting tissue ingrowth, and McAuslan discusses an implantable hydrogel to

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stimulate the attachment and growth of cells thereto. Accordingly, one of skill in the art would not be motivated to combine these either the Helland or McAuslan reference with the Vachon reference.

Claim 18 includes each limitation of its parent claim and is therefore also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

Claims 11-16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mar et al. (U.S. Patent No. 5,411,544) and in view of McAuslan is new (U.S. Patent No. 4,836,884) and Helland et al. (U.S. Patent No. 5,318,572).

Claims 11-16

Applicant traverses the rejection of claims 11-16. Applicant believes claim 11 is not obvious in view of the cited references since, even if combined the references do not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination a lead "wherein the lead body has a textured outer surface adapted to form a pseudo-intimal layer on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface," as recited in claim 11. In contrast, Mar discusses an implantable lead which includes etching to "help adhere the electrode in a specific and desirable location in the heart." (Col. 3, lines 35-36). The McAuslan reference discusses a modified implantable hydrogel. (Abstract). But nowhere in the McAuslan reference is the modified hydrogel specifically discussed as being applied to a lead body. Helland does not describe anything about the lead body outer surface.

Claims 12-16 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

In the alternative, claims 7 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon (U.S. Patent No. 5,861,023) and McAuslan is new (U.S. Patent No. 4,836,884) and Helland et al. (U.S. Patent No. 5,318,572), as applied to claims 1 and 17 above, and further in view of MacGregor (U.S. Patent No. 4,936,317).

Claim 7

Claim 7 depends from parent claim 1 and is not obvious in view of the cited references since even if combined the combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination "wherein the outer surface of the lead body is adapted such that a pseudo-intimal layer is formed on the outer surface when exposed to a bloodstream," as recited in parent claim 1. The discussion above regarding claim 1 is incorporated herein by reference. Reconsideration and allowance is respectfully requested.

Claim 18

Claim 18 depends from parent claim 17 and is not obvious in view of the cited references since, even if combined, the combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination "means for passively preventing clots on the lead body includes forming the lead body such that a pseudo-intimal layer is formed on an outer surface of the lead body when exposed to a bloodstream," as recited in parent claim 17. The discussion above regarding claim 17 is incorporated herein by reference.

Reconsideration and allowance is respectfully requested.

In the alternative, claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Mar et al. (U.S. Patent No. 5,411,544) and McAuslan is new (U.S. Patent No. 4,836,884) and Helland et al. (U.S. Patent No. 5,318,572), as applied to claim 11 above, and further in view of MacGregor (U.S. Patent No. 4,936,317).

Claim 15 depends from parent claim 11 and is not obvious in view of the cited references since even if combined the combination does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination "wherein the lead body has a textured outer surface adapted to form a pseudo-intimal layer on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface," as recited in parent claim 11. The discussion above regarding claim 11 is incorporated herein by reference. Reconsideration and allowance is respectfully requested.

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3267 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The <u>undersigned hereby certifies that this correspondence</u> is being filed using the USPTO'S electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Boy 1450, Alexandria, VA 22313.1450, units of Advandra April, 2006.

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